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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
(SAN FRANCISCO DIVISION)

LYLE TOOLE,

Plaintiff,

vs.

PFIZER, INC.;

Defendant.

Case No.: _____

PLAINTIFF LYLE TOOLE'S COMPLAINT; DEMAND FOR JURY TRIAL

Plaintiff, LYLE TOOLE, individually alleges:

I. BACKGROUND

1. This is an action for personal injuries and damages suffered by Plaintiff Lyle Toole ("Plaintiff") as a direct and proximate result of Pfizer, Inc.'s ("Pfizer") negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of sildenafil citrate tablets sold under the brand name Viagra® ("Viagra").

II. JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because Plaintiff is a citizen of the State of California, and Pfizer maintains its principal place of business and residence outside of California. The value of Plaintiff's claims exceeds the total of seventy-five thousand dollars ($75,000.00), exclusive of recoverable interest and costs. None of the causes of action stated herein has been assigned or otherwise given to any other court or tribunal.

3. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1332(a)(2) because Pfizer is a resident of a foreign state and does substantial business within the State of California and in this Judicial District, and otherwise maintains the requisite minimum contacts within the State of California. Additionally, Pfizer markets, advertises, distributes, sells, and receives substantial profits from the sales of Viagra in this District, and has and continues to conceal and make material omissions in this District, so as to subject it to *in personam* jurisdiction in this Judicial District. A substantial part of the events and omissions concerning the claims of Plaintiff occurred within this District. Furthermore, venue is proper in this District because Plaintiff purchased Viagra in this District.

III. PARTIES

4. Plaintiff, LYLE TOOLE, resides in the County of Monterey, State of California.

5. Defendant Pfizer, Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York, 10017. Defendant's registered agent is C T Corporation System, 818 West Seventh Street, Suite 930, Los Angeles, California 90017.

6. Pfizer, including its owners, employees, parent companies, subsidiaries, affiliates, and agents, developed, designed, manufactured, assembled, tested, inspected, marketed, promoted, advertised, warranted, distributed, sold, packaged, and/or provided warnings and instructions for Viagra.

7. Pfizer conducts substantial business within California through the marketing, distribution, and sale of Viagra.

IV. FACTS

A. Background

8. On March 27, 1998, the U.S. Food and Drug Administration approved a new drug application ("NDA") from Pfizer Pharmaceuticals Production Corporation Limited for the manufacture and sale of sildenafil citrate.

9. Sildenafil citrate, sold under the brand name Viagra, is an oral tablet prescribed to men with erectile dysfunction.

10. Erectile dysfunction is the medical designation for a condition in which a man

cannot achieve or maintain an erection sufficient for satisfactory sexual activity. Since achieving and/or maintaining an erection involves the brain, nerves, hormones, and blood vessels, any condition that interferes with any of these functional areas of the body may be causally related to an individual's erectile dysfunction. These problems become more common with age, but erectile dysfunction can affect a man at any age.

11. Viagra treats erectile dysfunction by inhibiting the secretion of phosphodiesterase type 5 ("PDE5"), an enzyme responsible for the degradation of cyclic guanosine monophosphate ("cGMP"). When the cGMP is not degraded by the PDE5, smooth muscles in the corpus cavernosum relax; this, in turn, permits an inflow of blood to the corpus cavernosum, creating an erection.

12. The National Institutes of Health estimate that erectile dysfunction affects as many as thirty million men in the United States.[1]

B. Prevalence of Viagra in Market

13. In its 2013 Annual Report, Pfizer states that it accumulated revenue exceeding $1,800,000,000 from worldwide sales of Viagra. This statistic is particularly significant in light of the fact that Pfizer lost exclusivity of Viagra throughout Europe in 2013, which in itself led to a drop in profits from the previous calendar year.

14. Viagra holds approximately 45% of the U.S. market share for erectile dysfunction medications.[2]

15. Pfizer estimates that Viagra has been prescribed to more than 35 million men worldwide.[3]

16. In 2012 alone, physicians wrote approximately eight million prescriptions for Viagra.[4]

B. Pfizer's Knowledge of Defect

[1] NIH Consensus Development Panel on Impotence (July 7, 1993).
[2] Jacque Wilson, *Viagra: The Little Blue Pill That Could*, CNN, Mar. 27, 2013, *available at*: http://www.cnn.com/2013/03/27/health/viagra-anniversary-timeline/index.html.
[3] Hilary Stout, *Viagra: The Thrill That Was*, N.Y. TIMES, June 5, 2011, *available at*: http://query.nytimes.com/gst/fullpage.html?res=9B06E3DF173FF936A35755C0A9679D8B63.
[4] Wilson, *supra* note 4.

17. Unbeknownst to most Viagra users, recent studies have shown that the cellular activity providing the mechanism of action for Viagra may also be associated with the development and/or exacerbation of melanoma.

18. The American Cancer Society states that melanoma is "the most serious type of skin cancer."[5]

19. According to the National Cancer Institute, part of the National Institutes of Health, melanoma is more likely than other skin cancers to spread to other parts of the body, thereby causing further tissue damage and complicating the potential for effective treatment and eradication of the cancerous cells.[6]

20. Several studies have linked the mechanism of action for Viagra to cell mutation cultivating melanomagenesis, or the creation of melanocytes which develop into melanoma.

21. A study published in 2011 found that treatment with Viagra can promote melanoma cell invasion.[7] Specifically, by inhibiting PDE5, Viagra mimics an effect of gene activation and therefore may potentially function as a trigger for the creation of melanoma cells.

22. A 2012 study published in the Journal of Cell Biochemistry also found that PDE5 inhibitors were shown to promote melanin synthesis,[8] which may exacerbate melanoma development.[9]

23. On April 7, 2014, an original study ("the JAMA study") was published on the website for the *Journal of the American Medical Association Internal Medicine* which, in light of the previous studies, sought to examine the direct relationship between sildenafil use and

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[5] American Cancer Society, *Skin Cancer Facts*, last revised March 19, 2014, *available at*: http://www.cancer.org/cancer/cancercauses/sunanduvexposure/skin-cancer-facts.

[6] National Cancer Institute, *Types of Skin Cancer*, last updated Jan. 11, 2011, *available at*: http://www.cancer.gov/cancertopics/wyntk/skin/page4.

[7] I. Aozarena, et al., *Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating The cGMP-Specific Phosphodiesterase PDE5A*, 19 CANCER CELL 45 (2011).

[8] X Zhang, et al., *PDE5 Inhibitor Promotes Melanin Synthesis Through the PKG Pathway in B16 Melanoma Cells*, 113 J. CELL BIOCHEM. 2738 (2012).

[9] F.P. Noonan, et al., *Melanoma Induction by Ultraviolet A But Not Ultraviolet B Radiation Requires Melanin Pigment*, 3 NATURE COMMUNICATIONS 884 (2012).

melanoma development in men in the United States.[10] The JAMA study was published in the journal's June 2014 edition.

24. Among 25,848 participants, the JAMA study reported that recent sildenafil users at baseline had a significantly elevated risk of invasive melanoma, with a "hazard ratio" of 1.84; in other words, the study participants who had recently used sildenafil exhibited an 84% increase in risk of developing or encouraging invasive melanoma.[11]

C. Consumer Expectations

25. Since Viagra's FDA approval in 1998, Pfizer has engaged in a continuous, expensive and aggressive advertising campaign to market Viagra to men worldwide as a symbol of regaining and enhancing one's virility.

26. Viagra has engaged in increasingly aggressive marketing techniques and strategies to promote the use of Viagra in the face of increasing pharmaceutical competition. By means of demonstration, a 2004 article in The Chicago Tribune cited industry reports stating that Viagra spent "tens of millions of dollars each month on direct-to-consumer advertising [ ]."[12]

27. Pfizer has also been criticized by regulators, physicians and consumer groups for its attempts to target younger men in their advertising. Doctors and federal regulators stated that "such ads sen[t] a confusing message to patients who might really benefit from the drug."[13]

28. While designing and formulating Viagra, Pfizer discovered or should have discovered that the drug's mechanism of action, the inhibition of PDE5, also presented a significant risk of exacerbating melanoma.

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[10] Wen-Qing Li, Abrar A. Qureshi, Kathleen C. Robinson, & Jiali Han, *Sildenafil Use and Increased Risk of Incident Melanoma in U.S. Men: A Prospective Cohort Study*, 174 JAMA INTERNAL MEDICINE 964 (2014).

[11] *Id*.

[12] Bruce Japsen, *Viagra's 2 Rivals Grab Market Share In A Year*, CHICAGO TRIBUNE, Sept. 23, 2004, *available at* http://articles.chicagotribune.com/2004-09-23/business/0409230283_1_viagra-erectile-levitra.

[13] Bruce Japsen, *Toned-Down Advertising Credited for Viagra Gains*, CHICAGO TRIBUNE, Feb. 8, 2007, *available at* http://articles.chicagotribune.com/2007-02-08/business/0702080063_1_viagra-erectile-pfizer-spokesman.

29. Despite these significant findings, Pfizer has made no efforts in its ubiquitous Viagra advertisements to warn users about the potential risk of developing melanoma that has been scientifically linked to its drug.

30. Members of the general public had no plausible means through which they could have discovered the significant risk of melanomagenesis associated with PDE5 inhibition.

31. Prescribing physicians would not have had the same level of access to the research and development conducted by Pfizer prior to its decision to manufacture Viagra for general public use.

32. Pfizer failed to communicate to the general public that the inhibition of PDE5 inherently necessary to the efficacy of Viagra would also present a significant risk of one's development or exacerbation of cancerous cells.

33. For example, no individual prescribed to use Viagra would believe or be expected to know that his use of Viagra would expose him to an increased risk of developing melanoma or exacerbating the growth of melanocytes already present in his body.

34. Pfizer expected or should have expected individuals who suffered from erectile dysfunction to ingest Viagra as a means to treat their condition.

35. Pfizer expected or should have expected physicians treating erectile dysfunction to prescribe Viagra as a means to treat the condition.

36. The risk presented by ingesting Viagra would be present from the moment of manufacture; that is, the user would not need to change or alter the drug itself or the means by which it was ingested in order for the drug to carry the same risk of harm as described herein.

D. Risks and Benefits of Viagra Use

37. At all times relevant hereto, Viagra was useful to some members of the population; namely, men diagnosed with erectile dysfunction.

38. Erectile dysfunction is not fatal, nor does it present any related symptoms or characteristics harmful to one's physical health; however, it did provide the benefit of allowing men with erectile dysfunction to achieve and maintain an erection.

39. Viagra also encourages the development of melanoma in the body of a user, thereby placing them at a significant health risk.

40. Pfizer manufactured, marketed and sold Viagra as a PDE5 inhibitor; however, the mechanism of action that made the drug effective in treating erectile dysfunction simultaneously enhanced the risk of the user developing melanoma.

41. At the time Viagra was formulated and manufactured, Pfizer knew or should have known that the drug posed a significantly heightened risk to users, specifically through the increased likelihood that those users would develop melanoma because of the chemical reactions inherent to the drug's functioning.

42. Through the testing and formulating of Viagra, and before the initiation of the drug's mass manufacture, Pfizer knew or should have known in the exercise of ordinary care that the chemical reactions inherent to Viagra's mechanism of action would present a cancer-related health hazard to potential future users.

43. The risk presented by the use of Viagra through PDE5 inhibition – a characteristic inherent to the drug's potential efficacy – was unquestionably far more significant than the benefit provided to its users.

44. Because the risk of using Viagra so greatly outweighs the benefits of such use, the drug presents an unreasonably dangerous risk when used in its intended condition.

E. Facts Regarding Plaintiff

45. Plaintiff began pharmaceutical treatment for erectile dysfunction in April 2001, when his physicians at the Palo Alto Veteran's Administration Hospital recommended that he begin taking Viagra.

46. Plaintiff continued to fill his Viagra prescriptions and take the drug regularly until at least December 2014.

47. On June 15, 2012, a Right Parotidectomy performed by Dr. Kenneth Nowak at Central Coast Head & Neck revealed melanoma in Mr. Tookle's neck.

48. On August 21, 2012, Plaintiff underwent a right modified radical neck dissection to remove the malignant melanoma.

49. Since first being diagnosed with melanoma, Plaintiff has had to remain vigilant in monitoring his skin for lesions.

50. Had Pfizer properly disclosed the melanoma-related risks associated with Viagra, Plaintiff would have avoided the risk of developing melanoma from Viagra use by deciding not to take Viagra at all; by severely limiting the dosage and/or length of time during which he used it; and/or by more closely monitoring the degree to which his Viagra consumption was adversely affecting his health.

51. As a direct, proximate, and legal result of Pfizer's negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug Viagra, Plaintiff suffered severe and permanent physical and emotional injuries. His physical injuries have included melanoma as well as the numerous surgeries necessitated by his skin cancer diagnosis. Plaintiff has endured not only physical pain and suffering but also economic loss, including significant expenses for medical care and treatment. Because of the nature of his diagnosis, he will certainly continue to incur such medical expenses in the future. As a result of these damages, Plaintiff seeks actual and punitive damages from Pfizer.

F. Summary

52. At all times relevant to this lawsuit, Pfizer engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Viagra for use among the general public.

53. For the duration of these efforts, Pfizer directed its advertising efforts to consumers located across the nation, including consumers in the State of California. Such efforts were also aimed at prescribing physicians across the nation, including prescribing physicians in the State of California.

54. At all times mentioned in this Complaint, Pfizer's officers and directors participated in, authorized, and directed the production and aggressive promotion of Viagra when they knew, or with the exercise of reasonable care should have known, of the risk of

developing melanoma associated with Viagra use. In doing so, these officers and directors actively participated in the tortious conduct which resulted in the injuries suffered by many Viagra users, including Plaintiff.

55. Pfizer purposefully downplayed, understated and outright ignored the melanoma-related health hazards and risks associated with using Viagra. Pfizer also deceived potential Viagra users by relaying positive information through the press, including testimonials from retired, popular U.S. politicians, while downplaying known adverse and serious health effects.

56. Pfizer concealed material information related to melanoma development from potential Viagra users.

57. In particular, in the warnings the company includes in its commercials, online and print advertisements, Pfizer fail to mention any potential risk for melanoma development and/or exacerbation associated with Viagra use.

58. As a result of Pfizer's advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for Viagra. If Plaintiff in this action had known the risks and dangers associated with taking Viagra, Plaintiff would have elected not to take Viagra and, consequently, would not have been subject to its serious side effects. Similarly, if Plaintiff's physicians had been aware of the risks and dangers associated with taking Viagra, they would have elected not to prescribe Viagra to Plaintiff or monitored his condition more closely.

VII. CAUSES OF ACTION

FIRST CAUSE OF ACTION
(Violation of Bus. & Prof. Code § 17200 *et seq*.)
(Unfairness)

59. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

60. California Business & Professions Code Section 17200 ("Unfair Competition Law" or "UCL") precludes unfair competition: *i.e.*, the employment of any unlawful, unfair or fraudulent business acts or practices; and, any unfair, deceptive, untrue or misleading

advertising (Cal. Bus. & Prof. Code Section 17500). This prohibition extends to any act, omission, or conduct affecting the rights of consumers within the State of California.

61. Pfizer has designed and continues to design, manufacture, market, sell, and place into the stream of commerce the Viagra purchased and used across California. Pfizer has failed and continues to fail to disclose and conceal the serious safety hazard posed by the design of Viagra—it does not warn Plaintiff or his physicians of the increased risk of developing melanoma as a result of using Viagra, and should not be purchased or used for that purpose.

62. Pfizer has been and remains obligated to disclose this material safety hazard because reasonable consumers expect Viagra to perform its only intended and reasonably expected function and purpose of allowing a user to achieve and maintain an erection. In failing to disclose this critical safety hazard, known to Pfizer but not to reasonable consumers like Plaintiff and his physicians, Pfizer engaged in and continue to engage in unfair conduct under Cal. Bus. & Prof. Code §17200. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the pattern of omission and concealment perpetrated by Pfizer against Plaintiff.

63. As a result of Pfizer's violations of the UCL, Plaintiff is entitled to appropriate equitable relief, including injunctive relief, and monetary relief in the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well as an award of attorneys' fees, costs, and expenses for prosecuting this action.

SECOND CAUSE OF ACTION
(Violation of Bus. & Prof. Code § 17200 *et seq.*)
(Fraudulent)

64. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

65. California Business & Professions Code Section 17200 ("Unfair Competition Law" or "UCL") precludes unfair competition: *i.e.*, the employment of any unlawful, unfair or fraudulent business acts or practices; and, any unfair, deceptive, untrue or misleading advertising (Cal. Bus. & Prof. Code Section 17500). This prohibition extends to any act, omission, or conduct affecting the rights of consumers within the State of California.

66. Pfizer has designed and continues to design, manufacture, market, sell, and place into the stream of commerce the Viagra purchased and used across California. Pfizer has failed and continues to fail to disclose and conceal the serious safety hazard posed by the design of Viagra—it does not warn Plaintiff or his physicians of the increased risk of developing melanoma as a result of using Viagra, and should not be purchased or used for that purpose.

67. Pfizer has been and remains obligated to disclose this material safety hazard because reasonable consumers like Plaintiff expect Viagra to perform its only intended and reasonably expected function and purpose of allowing them to achieve and maintain an erection. In failing to disclose this critical safety hazard, known to Pfizer but not to reasonable consumers like Plaintiff or his physicians, Pfizer engaged in and continue to engage in fraudulent conduct by omission under Cal. Bus. & Prof. Code §17200. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the pattern of omission and concealment perpetrated by Pfizer against Plaintiff.

68. As a result of Pfizer's violations of the UCL, Plaintiff is entitled to appropriate equitable relief, including injunctive relief, and monetary relief in the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well as an award of attorneys' fees, costs, and expenses for prosecuting this action.

THIRD CAUSE OF ACTION
(Violation of Bus. & Prof. Code § 17200 *et seq*.)
(Unlawfulness)

69. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

70. Pfizer's conduct is unlawful under the UCL because it violates Cal. Civ. Code § 1750, *et seq*. (hereinafter "Consumer Legal Remedies Act" or "CLRA"). Through omission and concealment, Pfizer has misrepresented and continues to misrepresent that Viagra: (a) has characteristics, uses or benefits that it does not have (Section 1770(a)(5)); and, (b) is of a particular standard, quality, or grade when they are of another (Section 1770(a)(7)). Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the pattern of misrepresentation by omission perpetrated by Pfizer against Plaintiff.

71. Were it not for Pfizer's unlawful conduct, Plaintiff would not have purchased Viagra. Instead, he would have purchased safe and reliable erectile dysfunction medication fit and safe for its intended purpose.

72. Plaintiff has and will continue to suffer injury in fact and lose money as a direct result of Pfizer's unfair competition in that he has had to undergo multiple surgeries and will continue to be required to undergo periodic skin checks to ensure against recurrence.

73. As a result of Pfizer's violations of the UCL, Plaintiff is entitled to appropriate equitable relief, including injunctive relief, and monetary relief in the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well as an award of attorneys' fees, costs, and expenses for prosecuting this action.

FOURTH CAUSE OF ACTION
(Strict Liability – Defective Design)

74. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

75. Pfizer formulated, manufactured, marketed, and sold Viagra with the intent that its users take the drug as a means of treating erectile dysfunction.

76. Plaintiff's physician prescribed Viagra to Plaintiff with the intent that Plaintiff purchase and ingest the drug to treat his erectile dysfunction.

77. Plaintiff's physician prescribed Viagra to Plaintiff with the belief and expectation that the drug's mechanism of action – the inhibition of the PDE5 enzyme – would effectuate Plaintiff's treatment goals in a foreseeable manner; i.e., Plaintiff would no longer suffer from the symptoms of erectile dysfunction.

78. Plaintiff, following the advice of his physician, purchased and ingested Viagra with the expectation that the drug would safely treat his erectile dysfunction.

79. However, the Viagra ingested by Plaintiff failed to treat his erectile dysfunction in a safe manner, even though he used the drug as it was intended to be used, as the drug's inhibition of PDE5 encouraged the development of melanoma throughout Plaintiff's internal systems and organs.

80. Viagra, as a drug, presented no open and obvious danger, but instead appeared to be a benign, harmless pill.

81. At all times relevant hereto, Viagra was useful to some members of the population; namely, men diagnosed with erectile dysfunction.

82. Erectile dysfunction is not fatal, nor does it present any related symptoms or characteristics harmful to one's physical health; however, it did provide the benefit of allowing men with erectile dysfunction to achieve and maintain an erection.

83. Viagra also encourages the development of melanoma in the body of a user, thereby placing them at a significant health risk.

84. The risk presented by the use of Viagra through PDE5 inhibition – a characteristic inherent to the drug's potential efficacy – was far more significant than the benefit provided to its users. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the defective design used by Pfizer in manufacturing and selling Viagra to Plaintiff.

85. Because the risk of using Viagra so greatly outweighs the benefits of such use, the drug presents an unreasonably dangerous risk when used in its intended condition.

86. Plaintiff did not change or alter the condition of the Viagra pills he ingested in any way, shape or form before ingesting them; instead, at the time he consumed the pills, they were in the same condition they were when those pills were manufactured and sold by Pfizer.

87. Because of the disproportionate risk presented by the use of Viagra, and/or because the drug did not perform as expected by a reasonable consumer, Viagra was unreasonably dangerous when it left the control of Pfizer.

88. As a direct and proximate result of Viagra's unreasonably dangerous design, Plaintiff has suffered significant pain, suffering, and economic damages incurred through cancer treatment necessitated by Viagra use.

FIFTH CAUSE OF ACTION
(Strict Liability – Failure to Warn)

89. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

90. While designing and formulating Viagra, Pfizer discovered or should have discovered that the drug's mechanism of action, the inhibition of PDE5, also presented a significant risk of exacerbating melanoma.

91. As a member of the general public, Plaintiff had no plausible means through which he could have discovered the significant risk of melanomagenesis associated with PDE5 inhibition.

92. Plaintiff's physician would not have had the same level of access to the research and development conducted by Pfizer prior to its decision to manufacture Viagra for general use.

93. Pfizer failed to communicate to Plaintiff or his physician that the inhibition of PDE5 inherently necessary to the efficacy of Viagra would also present a significant risk of one's development or exacerbation of cancerous cells.

94. If Pfizer had communicated the risk of developing or exacerbating melanomagenesis directly associated with Viagra use to Plaintiff's physician, he would not have prescribed Viagra to Plaintiff; severely limited the dosage he prescribed to Plaintiff; and/or closely monitored the length to which the Viagra was adversely affecting Plaintiff's health.

95. If Pfizer had communicated the risk of developing or exacerbating melanomagenesis directly associated with Viagra use to Plaintiff, Plaintiff would not have taken Viagra; severely limited the dosage he ingested; and/or closely monitored the length to which the Viagra was adversely affecting his personal health. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the failures to warn perpetrated by Pfizer against Plaintiff.

96. Plaintiff did not change or alter the condition of the Viagra pills he ingested in any way, shape or form before ingesting them; instead, at the time he consumed the pills, they were in the same condition they were when those pills were manufactured and sold by Pfizer.

97. As a direct and proximate result of Pfizer's failure to warn Plaintiff or his physician of the significant melanoma-related risks associated with Viagra's mechanism of

action, Plaintiff suffered significant pain, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

SIXTH CAUSE OF ACTION
(Negligence)

98. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

99. At all times relevant hereto, as the manufacturer of a product, Pfizer had a duty to design reasonably safe products.

100. At the time Viagra was formulated and manufactured, Pfizer knew or should have known that the drug posed a significantly heightened risk to users, specifically through the increased likelihood that those users would develop melanoma because of the chemical reactions inherent to the drug's functioning.

101. Through the testing and formulating of Viagra, and before the initiation of the drug's mass manufacture, Pfizer knew or should have known in the exercise of ordinary care that the chemical reactions inherent to Viagra's mechanism of action would present a cancer-related health hazard to potential future users like Plaintiff.

102. In proceeding to manufacture, market, and sell Viagra, Pfizer carelessly disregarded the hazard inherently presented by the drug.

103. Pfizer expected or should have expected individuals who suffered from erectile dysfunction, like Plaintiff, to purchase and ingest Viagra.

104. Pfizer expected or should have expected physicians treating erectile dysfunction, like Plaintiff's physician, to prescribe Viagra as a means to treat the condition.

105. Pfizer manufactured, marketed and sold Viagra as a PDE5 inhibitor; however, the mechanism of action that made the drug effective in treating erectile dysfunction simultaneously enhanced the risk of the user developing melanoma.

106. Through its design, Viagra's design makes it dangerous to its users. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the pattern of negligent behaviors perpetrated by Pfizer against Plaintiff.

107. As a direct and proximate result of the negligence committed by Pfizer in testing and ultimately selling Viagra, Plaintiff suffered significant pain, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

SEVENTH CAUSE OF ACTION
(Violation of Cal. Civil Code § 1790 *et seq.*)
(Breach of Express Warranty)

108. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

109. At all times relevant hereto, Pfizer expressly represented and warranted to Plaintiff and his healthcare providers, by and through statements made by Pfizer or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Viagra is safe, effective, and proper for its intended use.

110. These representations include, but are not limited to, the information disseminated in Pfizer's patient information and prescribing information publications, available on its website and on the FDA's website, since the drug entered the market.

111. The warranties expressly made by Pfizer through its marketing and labeling were false in that Viagra is unsafe.

112. Specifically, Viagra is unsafe in that its mechanism of action, the inhibition of the PDE5 enzyme, also increases the risk of the development and proliferation of melanocytic cells in the user's body.

113. Plaintiff's physician acted as a reasonable physician in relying on what he believed to be the superior knowledge, judgment, and access to research information possessed by Pfizer in choosing to prescribe Viagra to Plaintiff.

114. Plaintiff, acting as a reasonable consumer, relied on what he believed to be the superior skill, judgment, representations, and express warranties of Pfizer in deciding to purchase and use Viagra.

115. In direct reliance upon the warranties made by Pfizer that Viagra was safe to use in treating erectile dysfunction, Plaintiff's physician prescribed and Plaintiff used Viagra and

ultimately developed melanoma from the mechanism of action rendering the drug effective. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the pattern of omission and concealment perpetrated by Pfizer against Plaintiff.

116. As a direct and proximate result of the breach of warranty committed by Pfizer, Plaintiff suffered significant pain, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

EIGHTH CAUSE OF ACTION
(Violation of Cal. Civil Code § 1790 *et seq.*)
(Breach of Implied Warranty)

117. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

118. Plaintiff used Viagra in substantially the same condition it was in when it left the control of Pfizer.

119. Prior to the time that Plaintiff used Viagra, Pfizer implicitly warrantied to Plaintiff and his physician that Viagra was of merchantable quality, safe to use, and fit for the use for which it was intended.

120. Pfizer implicitly warrantied the safety of Viagra through a multimedia advertising campaign conducted over a span of several years, as Viagra had been on the market for several years prior to the time when Plaintiff was first prescribed Viagra.

121. Pfizer implicitly warrantied the merchantable quality of Viagra by opting to mass-produce and promote the prescription and sale of Viagra.

122. Pfizer implicitly warranted that Viagra was fit for the use for which it was intended by offering assertions through multimedia advertisements that the drug was used for the treatment of erectile dysfunction.

123. Plaintiff was and is unskilled in the research, design and manufacture of erectile dysfunction medications and therefore reasonably relied entirely on the skill, judgment and implied warranty of Pfizer in deciding to use Viagra.

124. Plaintiff's physician would not have had the same level of access to the research and development conducted by Pfizer prior to its decision to manufacture Viagra for general use.

125. Viagra was neither safe for its intended use nor of merchantable quality, as had been implicitly warranted by Pfizer, in that Viagra's mechanism of action – the inhibition of PDE5 – inherently presented a significant increase in the user's risk of developing melanoma.

126. As a direct and proximate result of the falsity of the warranties implicated by Pfizer's actions and omissions, Plaintiff suffered significant pain, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

VIII. PUNITIVE DAMAGES

127. Prior to the manufacturing, sale, and distribution of Viagra, Pfizer knew that said medication was in a defective condition as previously described herein, and knew that those who were prescribed the medication would experience and had already experienced severe physical, mental, and emotional injuries.

128. Pfizer, through their officers, directors, managers, and agents, knew that Viagra presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and, as such, Pfizer unreasonably subjected consumers of said drugs to risk of injury or death from using Viagra.

129. Pfizer and its agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Viagra knowing these actions would expose persons to serious danger in order to advance the company's market share and profits.

130. The acts, conduct, and omissions of Pfizer, as alleged throughout this Complaint, were willful and malicious.

131. Pfizer's unconscionable conduct warrants an award of exemplary and punitive damages against the company.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays judgment against Pfizer as follows:

ON THE FIRST CAUSE OF ACTION:

1. Equitable and/or injunctive relief as appropriate;
2. Monetary relief including restitution and fluid recovery;
3. Attorneys' fees, expenses, and costs of suit;
4. Interest; and
5. Such other and further relief as the Court deems proper.

ON THE SECOND CAUSE OF ACTION:

1. Equitable and/or injunctive relief as appropriate;
2. Monetary relief including restitution and fluid recovery;
3. Attorneys' fees, expenses, and costs of suit;
4. Interest; and
5. Such other and further relief as the Court deems proper.

ON THE THIRD CAUSE OF ACTION:

1. Equitable and/or injunctive relief as appropriate;
2. Monetary relief including restitution and fluid recovery;
3. Attorneys' fees, expenses, and costs of suit;
4. Interest; and
5. Such other and further relief as the Court deems proper.

ON THE FOURTH CAUSE OF ACTION:

1. Injunctive relief;
2. Damages including punitive damages;
3. Attorneys' fees, expenses, and costs of suit;
4. Interest; and
5. Such other and further relief as the Court deems proper.

ON THE FIFTH CAUSE OF ACTION:

1. Equitable and/or injunctive relief as appropriate;
2. Monetary relief including restitution and fluid recovery;
3. Attorneys' fees, expenses, and costs of suit;
4. Interest; and

5. Such other and further relief as the Court deems proper.

ON THE SIXTH CAUSE OF ACTION:

1. Equitable and/or injunctive relief as appropriate;
2. Monetary relief including restitution and fluid recovery;
3. Attorneys' fees, expenses, and costs of suit;
4. Interest; and
5. Such other and further relief as the Court deems proper.

ON THE SEVENTH CAUSE OF ACTION:

1. Equitable and/or injunctive relief as appropriate;
2. Monetary relief including restitution and fluid recovery;
3. Attorneys' fees, expenses, and costs of suit;
4. Interest; and
5. Such other and further relief as the Court deems proper.

ON THE EIGHTH CAUSE OF ACTION:

1. Equitable and/or injunctive relief as appropriate;
2. Monetary relief including restitution and fluid recovery;
3. Attorneys' fees, expenses, and costs of suit;
4. Interest; and
5. Such other and further relief as the Court deems proper.

DEMAND FOR JURY

Plaintiff Lyle Toole demands a trial by jury.

Dated: October 30, 2015.

/s/Trevor B. Rockstad
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